

ROUGH - Paul Galea

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VIDEO OPERATOR: We are now on the record.

My name is Catherine Smalfus, I am the videographer for Golkow Technologies. Today's date is December 9th, 2009 and the time is 9:51 a.m.

This video deposition is being held in New York, New York, In Re: Digitek Products Liability Litigation, for the United States District Court for the Southern District of West Virginia. The deponent is Paul Galea.

Will counsel please identify themselves.

MR. MILLER: Pete Miller, and I represent plaintiffs filed in Pennsylvania.

MS. CARTER: Meghan Carter from Motley Rice representing the plaintiffs.

MR. BLIZZARD: Ed blizzard from Houston. I represent the plaintiffs.

MS. GIBSON: Holly Gibson, representing the plaintiffs.

MR. LEE: Sean Lee from Shook, Hardy & Bacon, representing Mylan.

MR. MAZEY: Zack Mazey with Allen

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1 the manufacturing role and gone back into  
2 the world of QA?

3 A. That can be termed as correct.

4 Q. And what are you valid can  
5 dating as a validation officer?

6 A. As a validation officer, there  
7 were various projects going on so I was  
8 taking care of cleaning validation and  
9 facilities, our -- and equipment  
10 validation.

11 Q. And that was at the accident  
12 vision Totowa plant.

13 A. No. That has still been Malta  
14 at Actavis, Limited.

15 Q. Okay. What year did you  
16 transfer from Malta to Actavis, Totowa,  
17 physically?

18 A. 21st October, 2007.

19 Q. Was that at the request of the  
20 company or had you been requesting to  
21 transfer to the U.S.?

22 A. It -- it was a bit of both, I  
23 could say.

24 Q. What was -- as you were

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1 informed, what was the reason that the  
2 company requested it, that you transfer to  
3 Actavis Totowa?

4 A. The initial reason I was doing  
5 an assessment and helping out in the the  
6 harmonization of the group's corporate  
7 manual and that was basically the main  
8 reason.

9 Q. All right. Well, let's break  
10 that into two parts. What was the  
11 assessment that you believe that you were  
12 -- that you came here to work on?  
13 Assessment of what?

14 A. Basically, I came to make an  
15 assessment of Actavis Totowa, L.L.C.

16 Q. Overall assessment of the QA  
17 Department?

18 A. No. In general of the company  
19 from -- from a GMP perspective.

20 Q. Would you agree with me that  
21 there was some serious GMP issues in  
22 October of '07 at Actavis Totowa?

23 MR. ANDERTON: Objection.

24 You may answer.

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1 A. At this point it was me.

2 Q. Arriving in October of 2007  
3 to do an assessment of the GMP, who were  
4 you reporting to?

5 A. I was still reporting to -- to  
6 Actavis, Limited.

7 Q. Okay. We have -- excuse me,  
8 sir.

9 MR. MILLER: We have someone just  
10 checked in on the phone line. If that is  
11 correct, would you please identify yourself?

12 [Him him] see [S-EUG] company with  
13 Shelly Sanford's office.

14 MR. MILLER: Okay. Well, we've  
15 gotten started. If you would, please, put it on  
16 mute.

17 Thank you much.

18 BY MR. MILLER:

19 Q. So are arrived for two  
20 functions, assessment and harmonization if  
21 I said that right. The first was  
22 assessment of the GMP and you were  
23 reporting to who?

24 A. At this point now I report --

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1 in October of 2007, I report to Scott  
2 Talbot.

3 Q. And what was his title?

4 A. At that point he was the site  
5 head of quality at Actavis Totowa, L.L.C.

6 Q. GMP, it's good manufacturing  
7 procedures? Is that --

8 A. Practice.

9 Q. Good manufacturing practice.  
10 Is that used in Malta?

11 A. Yes.

12 Q. Is it identical to the GMP that  
13 we use here in the United States?

14 A. The governing bodies are  
15 different but it's I would say the spirit  
16 is similar.

17 Q. Do you agree that the GMP is in  
18 place in order to have a pharmaceutical  
19 company produce a safe product?

20 A. I believe that is the intent.

21 Q. How did you summarize the  
22 status of the GMP in -- after your arrival  
23 in October of 2007 to Scott Talbot?

24 MR. ANDERTON: Objection.

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1 I instruct the witness not to  
2 answer.

3 MR. MILLER: Why?

4 MR. ANDERTON: Self-critical  
5 analysis privilege.

6 BY MR. MILLER:

7 Q. In what state did you find the  
8 GMP of Actavis Totowa in October of 2007?

9 MR. ANDERTON: Objection. I  
10 instruct the witness not to answer.

11 MR. MILLER: Same grounds?

12 MR. ANDERTON: Yeah.

13 BY MR. MILLER:

14 Q. How long did you continue your  
15 assessment of GMP at Actavis Totowa?

16 A. I was there for initial  
17 assessment, which was around a week, and  
18 then there were subsequent visits to do  
19 further assessments.

20 Q. Did your assessment include  
21 actual inspection and review of the  
22 quality control labs within Actavis?

23 MR. ANDERTON: Objection.

24 You may answer.

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1 THE WITNESS: Yes.

2 BY MR. MILLER:

3 Q. What all did you physically  
4 review or inspect in order to make an  
5 assessment of the -- of the GMP systems in  
6 Actavis?

7 MR. ANDERTON: Objection.

8 I'm going to instruct the witness  
9 to -- to answer but not to reveal any of the  
10 findings or evaluations or substantive  
11 evaluations that you did. You may answer his  
12 question but in answering don't reveal any of  
13 your conclusions or findings.

14 THE WITNESS: The assessment was  
15 more of a general assessment, which -- which is  
16 -- which you would typically do when you're  
17 visiting for a short period of time.

18 BY MR. MILLER:

19 Q. So you went inside the QA lab.

20 MR. ANDERTON: Objection.

21 BY MR. MILLER:

22 Q. You can answer.

23 A. QC lab.

24 Q. I'm sorry. So you went inside

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1 the QC lab. Did you interview any lab  
2 techs there?

3 A. Not really.

4 Q. No?

5 A. Not really.

6 Q. What does not really mean?

7 A. I didn't interview anyone.

8 Q. Okay. Did you review lab  
9 analyst's logbooks?

10 MR. ANDERTON: Objection.

11 I instruct the witness not to  
12 answer. I mean, you're getting into the -- the  
13 content and the evaluation and the analysis.  
14 That's what's protected by the privilege.

15 MR. MILLER: I don't think if he  
16 looked at a logbook or not is protected by the  
17 privilege. I'm merely asking him what he looked  
18 at. I'm not asking him to reveal what he found  
19 in the logbook. Just what did he look at.

20 MR. ANDERTON: Ask your question  
21 again.

22 BY MR. MILLER:

23 Q. Did you review any lab logbooks  
24 in your assessment of the GMP procedures

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1 at Actavis?

2 MR. ANDERTON: Objection.

3 You may answer.

4 THE WITNESS: I did not  
5 specifically review but I can say that I looked  
6 at logbooks.

7 BY MR. MILLER:

8 Q. What were you informed of were  
9 -- were the issues with GMP prior to your  
10 assessment?

11 A. I was not informed of any GMP  
12 issues.

13 Q. Just got a call in Malta and  
14 said go to Actavis Totowa and make an  
15 assessment of their GMP program?

16 A. Yes, I would say that is  
17 correct.

18 Q. You agreed with me earlier that  
19 there are serious issues at the -- with  
20 GMP at Actavis Totowa. Did you have that  
21 understanding prior to your assessment?

22 MR. ANDERTON: Objection.

23 That totally mischaracterizes the  
24 witness's testimony.

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1 MR. MILLER: Well --

2 THE WITNESS: I -- I did not agree  
3 that there were serious issues.

4 MR. MILLER: Okay. I'll ask -- all  
5 right. Let me ask this: Do you believe there  
6 were serious issues with the GMP procedures at  
7 Actavis Totowa prior to your arrival in October  
8 of 2007.

9 MR. ANDERTON: Objection.

10 I instruct the witness not to  
11 answer.

12 MR. MILLER: Why are you asking him  
13 not to answer that?

14 MR. ANDERTON: Because again,  
15 that's his -- that's the conclusion that he's  
16 reached as he's conducting this analysis.

17 MR. MILLER: I'm back it up. I'm  
18 asking before he ever got there. There's no  
19 conclusion because he hasn't done an assessment.

20 MR. ANDERTON: He also told you  
21 that he didn't have any knowledge about the  
22 operations before he got there. You're asking  
23 him -- you didn't ask him about before he got  
24 there.

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1 MR. MILLER: I'm asking him what  
2 his understanding was, what his mental  
3 understanding was, before he got there and I'm  
4 entitled to that.

5 MR. ANDERTON: All right. Then I  
6 would ask you to make sure that that aspect is  
7 incorporated in your question because it wasn't  
8 as you phrased it then.

9 MR. MILLER: All right. I'll  
10 rephrase it.

11 MR. ANDERTON: Okay.

12 BY MR. MILLER:

13 Q. What was your mental  
14 understanding of the status of the GMP  
15 protocol procedures at Actavis Totowa  
16 prior to your arrival in October of 2007?

17 A. I had no real understanding of  
18 what I was going to be assessing.

19 Q. Did you have a mental  
20 understanding prior to October of 2007 of  
21 things are going really good, I'm going  
22 there to learn how to do GMP right?

23 A. As I already said, I had no  
24 understanding of the company before the

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1 time I went there.

2 Q. How long did your GMP  
3 assessment last after your arrival? How  
4 long did you continue in that role?

5 A. I was there from the initial  
6 visit was from the second of February, I  
7 think, to around about the 9th. A week in  
8 total.

9 Q. So you continued an assessment  
10 from October of '07 until February of '09.

11 A. No. No. That is incorrect.  
12 What I am saying is my initial assessment  
13 was February 2nd, 2007, until February  
14 9th, around about, 2007.

15 Q. Okay. Well, I'm sorry. I  
16 thought you originally arrived 25 October,  
17 2007.

18 A. No. My answer to your question  
19 was, I started as an employee to Actavis  
20 Totowa on the 21st of October 2007. My  
21 first visit was in February of 2007.

22 Q. And that visit for for roughly  
23 a week.

24 A. Around about.

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1 Q. And was that strictly for  
2 assessment or was that for the  
3 harmonization of the company as well?

4 A. It was for the assessment.

5 Q. Assessment.

6 Did you make any other visits to  
7 Totowa prior to you permanently coming here in  
8 12th October of 2007?

9 A. Yes, I did.

10 Q. And when were the other visits?

11 A. Roughly, I can say that one was  
12 in March.

13 Q. Of '07.

14 A. Of '07. I believe one was  
15 around about the end of May. Another  
16 visit was around about June to July. And  
17 I believe the final visit was sometime in  
18 August.

19 Q. And were each of these as well  
20 for the purpose of assessment of the GMP  
21 program?

22 A. Not really. The initial visit  
23 was more of an assessment. Subsequently  
24 it was also more to look at harmonization.

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1 Q. So the March -- March visit you  
2 agree was assessment and harmonization?

3 A. Yeah. They -- they rolled over  
4 into each other more or less.

5 Q. Okay. And you say that's true  
6 for all, the March, the May, the June and  
7 the August?

8 A. I wouldn't say assessments. I  
9 would say more leaning towards  
10 harmonization.

11 Q. Who was it in the company, in  
12 Actavis, either in Malta or here in the  
13 United States or anywhere else, that gave  
14 you the orders or sent you to Actavis  
15 Totowa for this assessment?

16 A. The head of quality for Actavis  
17 Group contacted me.

18 Q. And he contacted you prior to  
19 your first visit in February of 2007?

20 A. She.

21 Q. She. What was her title? I'm  
22 sorry. What was her name?

23 A. Gudrun.

24 Q. Could you spell that?

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1           A.       G-U-D-R-U-N, Eyolfsdottir. So  
2       E-Y-O-L-F-S-D-O-T-T-I-R.

3           Q.       Now, would her office be in --  
4       in Iceland?

5           A.       Yes.

6           Q.       And did she communicate with  
7       you by phone or letter or E-mail or some  
8       other way in order to give you  
9       instructions for this trip?

10          A.       Phone.

11          Q.       Phone? And what did she inform  
12       you on that phone call that your mission  
13       was going to be on your trip?

14                   MR. ANDERTON: Objection.

15                   You may answer.

16                   THE WITNESS: She asked me if I  
17       would be willing to go over to the U.S. to make  
18       an assessment of Actavis Totowa, L.L.C.

19       BY MR. MILLER:

20          Q.       And did she indicate one way or  
21       the other what she thought you were going  
22       to find when you arrived?

23                   MR. ANDERTON: Objection.

24                   You may answer.

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1 THE WITNESS: No.

2 BY MR. MILLER:

3 Q. Was any communication between  
4 you and her done in -- in -- via E-mail or  
5 writing or any other form?

6 A. We communicated by phone.

7 Q. Did you communicate with Scott  
8 Talbot prior to your arrival?

9 A. No.

10 Q. Once the assessment took place,  
11 was there communication between you and  
12 Gudrun or Scott Talbot or anyone else  
13 regarding the assessment via E-mail or  
14 letter?

15 A. Yes, I believe there was.

16 Q. There was which? E-mail or  
17 letter or both?

18 A. E-mail.

19 Q. How often would you E-mail back  
20 and forth with Mrs. Gudrun or Scott --  
21 Scott Talbot?

22 A. Cannot recall.

23 Q. Once a week? Twice a week?

24 A. Probably more on a monthly

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1 basis, I would say.

2 Q. Was there any report associated  
3 with the E-mails? Like this is the  
4 monthly assessment report? Was there  
5 anything that -- that you kept, a diary, a  
6 log, an Excel spreadsheet regarding your  
7 assessment?

8 A. I believe I sent one report  
9 alone.

10 Q. Do you recall when that report  
11 was?

12 A. Probably sometime in -- after  
13 the February visit.

14 Q. And would you have sent that to  
15 Mr. Talbot?

16 A. No.

17 Q. You sent that directly to  
18 Mrs. I guess her first name is Gudrun; is  
19 that right?

20 A. I probably sent it to the q.s.  
21 D department. It's the quality systems  
22 department, which takes care of internal  
23 audits for the group.

24 Q. And if you would have E-mailed

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1 that report, would it have been an  
2 attachment to the QSD?

3 A. Typically, yes.

4 Q. And who specifically would you  
5 have written that report to? Do you  
6 recall?

7 A. Specifically, I cannot recall  
8 to whom.

9 Q. Would it have been who was in  
10 charge of the QSD at that time?

11 A. Most probably, yes.

12 Q. But you do agree that there was  
13 also E-mail communication between yourself  
14 and -- and Gudrun following your -- your  
15 assessment or during your assessment?

16 A. I believe most of the  
17 conversations were phone conversations.

18 Q. But do you recall ever sending  
19 Gudrun an E-mail?

20 A. I cannot exclude it. On the  
21 top of my head, I cannot say yes or no  
22 but...

23 Q. How did the makeup of the  
24 assessment change? You indicated that it

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1 assessment.

2 MR. MILLER: Okay.

3 BY MR. MILLER:

4 Q. That tailing end, did you share  
5 any of the information you obtained in the  
6 tailing end of the assessment in the March  
7 visit with anyone?

8 A. Not that I recall.

9 Q. Did your report following the  
10 February visit give any recommendations to  
11 the company of what you thought needed to  
12 be done with the GMP program at Actavis --

13 MR. ANDERTON: Objection.

14 BY MR. MILLER:

15 Q. -- Totowa?

16 MR. ANDERTON: Objection.

17 I instruct the witness to answer  
18 without revealing any of the substance of the  
19 report?

20 THE WITNESS: Yes. There were  
21 recommendations.

22 BY MR. MILLER:

23 Q. Do you recall how many  
24 recommendations?

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1 MR. ANDERTON: Objection.

2 I instruct the witness not to  
3 answer.

4 MR. MILLER: How many? I'm not  
5 getting into the specifics of what they are, I'm  
6 looking --

7 MR. ANDERTON: That's -- that's  
8 substantive content.

9 MR. BLIZZARD: Let me state for the  
10 record, however, that we believe we're entitled  
11 to all of it. We may be carving around your  
12 claimed privilege but we're entitled to this, in  
13 our view so we'll be back after we talk to the  
14 judge about it.

15 MR. ANDERTON: Your objection is  
16 noted. I mean, there's -- in the MDL certainly  
17 there is a clear order -- first of all, there's  
18 the privilege issue protecting this  
19 information. Second of all, in the MDL there's  
20 a clear order protecting information relating to  
21 drugs other than Digitek. We believe Mr. Miller  
22 identifying himself as a representative of the  
23 Pennsylvania litigants while also occupying a  
24 seat on the PSC is a clear and direct effort to

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1 circumvent his obligations as a member of the  
2 PSC. We think it's inappropriate. We'll  
3 tolerate it because at the end of the day he's  
4 going to have his right to question the witness  
5 anyway and we can't stop that from happening but  
6 we think it's a clear breach of your duties as a  
7 member of the PSC and an effort to get around  
8 the coordination and cooperation provisions  
9 imposed on you under PTO 22 and the other MDL  
10 PTO orders so, you know, we're asserting our  
11 privilege, Mr. Blizzard. We appreciate your  
12 comments but...

13 MR. BLIZZARD: Well, I just want to  
14 make clear that we believe we're entitled to the  
15 assessment that was done by this witness.  
16 Furthermore, we'd say that the -- the PTO that  
17 relates to the order of questioning says that if  
18 the -- if the questioning order cannot be agreed  
19 upon between the states and the MDL, then this  
20 order of questioning shall apply. Mr. Miller  
21 and I have agreed that he would go first in this  
22 deposition, I'm going to go first in tomorrow's  
23 deposition so it's a sharing that's agreed upon  
24 by counsel who represent the states and counsel

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1 for the MDL.

2 Secondly, we don't think that there  
3 is a clear order that says we can't ask  
4 questions that may relate to other drugs. There  
5 is an order but the order pertains to whether  
6 you've had to produce documents and it was an  
7 essential part of your argument there and is  
8 reflected in the order that you would have to  
9 spend millions of dollars producing he's  
10 documents regarding other drugs so the judge did  
11 a balancing sort of assessment of whether or not  
12 it was required that you produce those  
13 documents. It did not pertain to questioning of  
14 the witnesses and a balancing of the interest  
15 here we believe would balance in favor of being  
16 able to ask these questions so that's our view.

17 MR. ANDERTON: And I appreciate --

18 MR. BLIZZARD: And that view will  
19 be expressed to the Court.

20 MR. ANDERTON: And I appreciate  
21 that. And your characterization of the language  
22 of PTO 27 and its limit -- and characterizing it  
23 as being limited to the documents and not  
24 extending to questioning of witnesses is -- is

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1 inconsistent and contrary to our view. The  
2 language is clear on its face. Magistrate Judge  
3 Stanley very clearly and very expressly  
4 characterized her ruling of an expansion of the  
5 scope of discovery. A limited expansion of the  
6 scope of discovery. And obviously, questioning  
7 the witnesses at a deposition constitutes  
8 matters that fall within the scope of  
9 discovery. So PTO 27 and its corresponding PTO  
10 30 or PTO 37. Judge Goodwin affirming the  
11 magistrate's ruling clearly set the boundaries  
12 of the scope of discovery in the litigation with  
13 respect to information relating to other drugs  
14 other than digital. We're going to continue to  
15 take that position. We appreciate your position  
16 and the issue is our mind has been resolved in  
17 the MDL. There's a motion pending in the  
18 Pennsylvania litigation. That will resolve as  
19 it is resolved and we'll go forward from there.

20 MR. BLIZZARD: Okay. Well, in our  
21 view, you're obstructing discovery. It's clear  
22 from the record today. We're asking about GMP  
23 and not about other drugs and you're instructing  
24 the witness not to answer questions clearly

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1 about GMPs that also apply to the manufacture of  
2 Digitek.

3 MR. ANDERTON: I'm instructing the  
4 witness not to answer the substance of an  
5 analysis that falls under a privilege protecting  
6 that information.

7 MR. BLIZZARD: I've never heard of  
8 the privilege before but perhaps you'll  
9 enlighten us later.

10 MR. ANDERTON: Ready, Mr. Miller?

11 MR. MILLER: I am ready.

12 BY MR. MILLER:

13 Q. Now I want to talk to your  
14 second function and your trips in 2007 to  
15 Actavis Totowa, harmonization. Explain  
16 what that means to you. What was your  
17 goal there?

18 A. Okay. As the word is a bit of  
19 a fancy word but basically, a  
20 harmonization is to look at the various  
21 companies and see that they are working  
22 under the same umbrella. When you have a  
23 big corporation, it's something that you  
24 typically would like to do.

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1 A. I would say no.

2 Q. Were you ever asked to produce  
3 that as part of this case?

4 MR. ANDERTON: Objection.

5 You may answer.

6 THE WITNESS: No.

7 BY MR. MILLER:

8 Q. When was the decision made that  
9 you would come here permanently in October  
10 by continuing your visits that had been  
11 done earlier in 2007?

12 MR. ANDERTON: Objection.

13 You may answer.

14 THE WITNESS: I believe the -- the  
15 actual decision was made around about September  
16 of 2007.

17 BY MR. MILLER:

18 Q. And what was your title when  
19 you arrived 21 October, 2007?

20 A. Quality systems director.

21 Q. What is the job function of a  
22 quality systems director?

23 A. I can answer what my job  
24 functions were because different companies

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1 THE WITNESS: The discussion was,  
2 if I can recollect, looking at the general  
3 systems.

4 BY MR. MILLER:

5 Q. At the general systems. So  
6 there -- you -- even when you were doing  
7 your assessment roughly the same time as  
8 this letter came out, you -- you were  
9 never given any instruction or guidance to  
10 look at GMP as it pertained to any  
11 particular products that were being made.  
12 Is that correct?

13 MR. ANDERTON: Objection.

14 You may answer.

15 THE WITNESS: No.

16 BY MR. MILLER:

17 Q. And in fact, the GMP at Actavis  
18 Totowa, the procedures of GMP as used by  
19 the quality group pertained to all drugs,  
20 all products that were manufactured.

21 MR. ANDERTON: Objection.

22 You may answer.

23 THE WITNESS: Procedures are not  
24 product specific. Procedures tell you how to

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1 perform an operation.

2 BY MR. MILLER:

3 Q. They're -- they're not product  
4 specific, therefore, they -- they apply to  
5 -- to all products.

6 A. Procedures do not necessarily  
7 apply to a product.

8 Q. Okay. Well, my question is,  
9 you agree that -- that Actavis had issues  
10 with their enforcement or -- or use of GMP  
11 in the quality group in 2007.

12 MR. ANDERTON: Objection.

13 That's not your question and that  
14 mischaracterizes his testimony.

15 MR. MILLER: It's okay to answer?

16 THE WITNESS: Can you rephrase that  
17 for me?

18 MR. MILLER: Certainly.

19 BY MR. MILLER:

20 Q. There were issues in the  
21 quality group of Actavis Totowa in 2007  
22 regarding their use of GMP.

23 MR. ANDERTON: Objection.

24 MR. MILLER: It's okay to answer.

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1 Q. When?

2 A. Over the course of last week  
3 and this week.

4 Q. On how many different days?

5 A. Two days.

6 Q. How many hours per day?

7 A. One day four or five hours.

8 The other day, a couple of hours.

9 Q. Were you shown any documents  
10 that you might be asked about in the  
11 deposition?

12 A. No.

13 Q. Okay. Now, you're not from the  
14 United States, you're from Malta; correct?

15 A. Yes.

16 Q. And had -- had you ever -- had  
17 you visited the United States before  
18 February of 2007?

19 A. No.

20 Q. And what was your job before  
21 you came to the United States for Actavis?

22 A. I was QA manager at Actavis,  
23 Limited.

24 Q. And Actavis, Limited, was their

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1 headquarters in Malta?

2 A. It is a subsidiary of the  
3 headquarters in Iceland.

4 Q. Okay. So the group that you  
5 worked for in Malta was a subsidiary of  
6 the headquarters of Actavis, which is  
7 located in Iceland; right?

8 A. That is correct.

9 Q. And you were the QA manager?

10 A. Yes.

11 Q. And was there anybody in the  
12 Malta operation that you reported to in  
13 quality?

14 A. Yes.

15 Q. Who was that?

16 A. Mr. Joseph Bondin.

17 Q. How do you spell that?

18 A. That's J-O-S-E-P-H, Joseph, and  
19 Bondin is B-O-N-D-I-N.

20 Q. And what was his position?

21 A. He was QA manager for the  
22 division.

23 Q. And who did he report to?

24 A. At the group level he reports

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1 to Gudrun Eyolfisdottir.

2 Q. Okay. So he reports to the  
3 person in Iceland who's in charge of  
4 quality for the entire organization?

5 A. Within quality he reports to  
6 Gudrun.

7 Q. Okay. Now, when did you first  
8 find out that you were going to the United  
9 States?

10 A. Around about the end of  
11 December of 2006.

12 Q. Okay. And you -- you testified  
13 about some of this earlier but I want to  
14 make sure I'm clear on it. How were you  
15 notified that you were going to the United  
16 States?

17 A. I was asked if I was willing to  
18 go and make an assessment at Actavis  
19 Totowa, L.L.C.

20 Q. And who asked you that?

21 A. Gudrun Eyolfisdottir.

22 Q. Okay. So is it -- am I  
23 understanding correctly that you received  
24 a phone call from Gudrun asking you to do

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1           A.       I would say Scott Talbot, Dan  
2     Bitler, Jasmine Shah, Elina Novikov,  
3     that's what I would say.

4           Q.       Okay. Was there a VP of  
5     Actavis that was located in the United  
6     States in charge of quality?

7                   MR. ANDERTON: Objection.

8                   You may answer.

9     BY MR. BLIZZARD:

10          Q.       During the time frame that you  
11     first came to the United States in, as you  
12     said, early of 2007, was there a VP of  
13     quality located here in the United States?

14          A.       Yes.

15          Q.       Who was that VP of quality?

16          A.       Nasrat Hakim.

17          Q.       I'm sorry. You're going to  
18     have to spell that one for me.

19          A.       N-A-S-R-A-T, that's the name.  
20     Surname is Hakim, H-A-K-I-M.

21          Q.       Okay. Now, do you know why you  
22     were assigned the responsibility of doing  
23     this assessment, this assessment of  
24     whether the company was in compliance with

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1 GMPs rather than Scott Talbot, Dan Bitler,  
2 Jasmine Shah, Elina Novikov or Nasrat  
3 Hakim?

4 MR. ANDERTON: Objection;  
5 mischaracterizes his testimony.

6 You may answer.

7 THE WITNESS: I was assigned to do  
8 this assessment because I am a corporate or at  
9 least I was at the time a corporate auditor for  
10 the Actavis Group.

11 MR. BLIZZARD: Corporate auditor.  
12 Okay.

13 BY MR. BLIZZARD:

14 Q. So who -- by the way, who were  
15 you employed by as of the time you were  
16 doing this assessment?

17 A. Actavis, Limited.

18 Q. Okay. And that was a separate  
19 corporation from Actavis Totowa; correct?

20 A. Yes.

21 Q. So you were doing sort of an  
22 outside audit of Actavis Totowa, weren't  
23 you?

24 A. Yes.

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1 Q. After -- was there anybody at  
2 all who had the function -- same function  
3 as your job responsibilities prior to the  
4 time you came here?

5 A. That's a bad question. Let me  
6 ask it a different way. I think I already  
7 have so I'll -- I'll move on to something  
8 else.

9 Now, you've talked about GMPs.  
10 That's an acronym. Do you know what an acronym  
11 is?

12 A. Yes.

13 Q. What is -- what is it an  
14 acronym for?

15 A. Good manufacturing practice.

16 Q. And what are good manufacturing  
17 practices?

18 MR. ANDERTON: Objection.

19 You may answer,

20 THE WITNESS: There's a long list.

21 MR. BLIZZARD: Okay.

22 BY MR. BLIZZARD:

23 Q. I'm not asking you to list  
24 them. I'm asking you to generally

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1 describe so that the jury understands what  
2 they are, what are good manufacturing  
3 practices?

4 A. Okay. They're a set of rules  
5 and guidances which direct you in the  
6 manufacturing and packaging and testing of  
7 your product.

8 Q. And what is the purpose of  
9 these rules and guidances?

10 MR. ANDERTON: Objection; asked and  
11 answered.

12 You may answer.

13 THE WITNESS: The objective is to  
14 manufacture a tablet which is good for human  
15 use.

16 MR. BLIZZARD: Okay.

17 BY MR. BLIZZARD:

18 Q. So is it part of the good  
19 manufacturing practices to assure safety?

20 A. Yes.

21 Q. Is it also part of good  
22 manufacturing practices to assure that the  
23 pills have the appropriate identity,  
24 strength and quality and purity?

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1 MR. ANDERTON: Objection.

2 You may answer.

3 THE WITNESS: Yes.

4 BY MR. BLIZZARD:

5 Q. Is it the standard of care  
6 within the manufacturing of  
7 pharmaceuticals industry to follow good  
8 manufacturing practices?

9 MR. ANDERTON: Objection.

10 You may answer,

11 THE WITNESS: Yes.

12 BY MR. BLIZZARD:

13 Q. And if a company fails to  
14 follow good manufacturing practices, is it  
15 in violation of the standard of care?

16 MR. ANDERTON: Objection.

17 You may answer.

18 THE WITNESS: Yes.

19 BY MR. BLIZZARD:

20 Q. Now, you've also mentioned  
21 another term earlier today called SOPs and  
22 we use that a lot as shorthand and I want  
23 to make sure the jury understands what an  
24 SOP is. So could you explain what an SOP

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1 involved in the quality system improvement  
2 plan?

3 A. Right now I have been given  
4 that task under my group and that's been  
5 for five months, I would say.

6 Q. Okay. So you've only been  
7 involved since 2009; correct?

8 A. Yes. Directly.

9 Q. Well, were you involved  
10 indirectly before that?

11 A. Yes.

12 Q. When were you first involved  
13 indirectly?

14 A. After I was hired in 2007.

15 Q. And when was that? Exactly you  
16 mean after you were hired in October of  
17 2007?

18 A. Yes.

19 Q. Okay. So you became a  
20 full-time employee of Actavis Totowa in  
21 October of 2007; correct?

22 A. Yes.

23 Q. Before that you were employed  
24 by a separate corporation called Actavis,

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1 Limited; correct?

2 A. Yes.

3 Q. And it was only after October  
4 of 2007 that you came indirectly involved  
5 with the quality systems improvement plan;  
6 correct?

7 A. Yes.

8 Q. And what was your indirect  
9 involvement?

10 A. The quality systems improvement  
11 plan as it stands is to create actions for  
12 improvement or -- or tasks. So I was  
13 given tasks on occasion which my  
14 department had to fulfill.

15 Q. Have you ever heard of the  
16 phrase if it ain't broke, don't fix it?

17 A. In America, I've heard that.

18 Q. Okay. So was there -- was the  
19 quality system broken before this quality  
20 system improvement plan was instituted?

21 MR. ANDERTON: Objection.

22 You may answer.

23 THE WITNESS: I cannot say that.

24 MR. BLIZZARD: Let me hand you what

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1 plan and a quality -- quality systems  
2 improvement plan, both are intended to  
3 address deficiencies in the quality  
4 department, are they not?

5 A. No, that is not correct.

6 Q. Okay. They're both intended to  
7 address deficiencies in the company;  
8 correct?

9 MR. ANDERTON: Objection.

10 THE WITNESS: That is not correct.

11 MR. BLIZZARD: Okay.

12 BY MR. BLIZZARD:

13 Q. So are corrective action plans  
14 part of the routine business of the  
15 company?

16 A. Yes.

17 Q. And is it also a routine part  
18 of the company business to do assessments  
19 of the company's compliance with GMPs?

20 A. Yes.

21 Q. And when you do a assessment of  
22 the company's compliance with GMPs, you're  
23 not necessarily being critical of every  
24 aspect of the company's operations, are

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1 BY MR. BLIZZARD:

2 Q. Would you characterize your  
3 assessment that you did beginning in  
4 February of 2007 to be purely subjective  
5 evaluation or more of a factually  
6 objective assessment whether the company  
7 was in compliance with GMPs?

8 MR. ANDERTON: Objection.

9 I'm going to instruct the witness  
10 not to answer.

11 BY MR. BLIZZARD:

12 Q. Now, well, this -- this  
13 question clearly is designed to -- to  
14 determine whether or not this claimed  
15 privilege you're asserting is a viable  
16 privilege so --

17 MR. ANDERTON: In a the privilege  
18 you're E.

19 MR. BLIZZARD: You're not  
20 instructing -- the privilege has been rejected  
21 by most jurisdictions, as I understand it, in  
22 the quick review that we've done, including the  
23 State of Pennsylvania, who has specifically  
24 rejected it.

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1 MR. ANDERTON: I'm sorry. Are you

2 --

3 MR. BLIZZARD: Yes, I'm saying that  
4 the privilege in this case does not exist and  
5 I'm just exploring with the witness at this  
6 point in time whether or not this was a self  
7 critical subjective analysis.

8 MR. ANDERTON: Well, and in  
9 response to your speech, I want to clarify a few  
10 points just so that we're clear. Is this the  
11 same privilege you claimed earlier on the record  
12 you had never heard of before.

13 MR. BLIZZARD: Yes, it is.

14 MR. ANDERTON: First time today  
15 you'd heard of it?

16 MR. BLIZZARD: Correct. I've never  
17 seen it asserted in any single case that I've  
18 handled before and I've handled a few.

19 MR. ANDERTON: You mentioned the  
20 viability of this privilege in Pennsylvania. If  
21 I understand correctly, Mr. Blizzard, you're  
22 conducting your examination under the auspices  
23 of the PSC in the MDL; correct.

24 MR. BLIZZARD: I am -- I am

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1 conducting this examination as a lawyer on  
2 behalf of my client and I happen to be a PSC  
3 member so yes, I am acting on behalf of the PSC  
4 here, as I am on behalf of my client.

5 MR. ANDERTON: So that we're clear,  
6 however, you're not conducting any examination  
7 with respect to any cases pending in the  
8 Pennsylvania litigation; correct.

9 MR. BLIZZARD: True, true.

10 MR. ANDERTON: Is that accurate?

11 MR. BLIZZARD: True. Although this  
12 deposition may be utilized in that jurisdiction.

13 MR. ANDERTON: But your examination  
14 is not being conducted in the context of the  
15 Pennsylvania -- you guys are making a --

16 MR. BLIZZARD: I'm not here to be  
17 cross-examined. I'm telling you that I'm a  
18 lawyer here asking questions and I am a PSC  
19 representative here today and I also represent  
20 my client and none of my clients have cases  
21 pending in Pennsylvania.

22 MR. ANDERTON: Okay. So you're not  
23 --

24 MR. BLIZZARD: Do not ask me

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1 another question because I'm not answering your  
2 specific question.

3 MR. ANDERTON: You may choose not  
4 to answer it but I'm going to make my record,  
5 okay? Because you guys are making a big deal  
6 out of whose wearing what has and which order  
7 may or may not apply and we are certainly  
8 entitled to be clear on the record where you're  
9 asking questions, from the platform from which  
10 you're asking questions and conducting your  
11 examination. So to be clear, if you choose not  
12 to answer, then the record will stand as is,  
13 it's true that you're not asking questions in  
14 the context of the Pennsylvania litigation;  
15 correct?

16 MR. BLIZZARD: I've made myself  
17 clear. I am here on behalf of my clients, none  
18 of whom have cases pending in Pennsylvania and I  
19 am here as a member of the PSC to ask questions.

20 MR. ANDERTON: Okay.

21 MR. BLIZZARD: All right. So your  
22 -- your instruction for him to not answer the  
23 last question remains? I don't have to re-ask  
24 it?

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1 MR. ANDERTON: Can you read that  
2 back, please.

3 (The court reporter read the  
4 requested portion of the record.)

5 MR. ANDERTON: My instruction  
6 stands.

7 MR. BLIZZARD: Okay.

8 BY MR. BLIZZARD:

9 Q. Now, let's talk about this  
10 document that has been marked as Exhibit  
11 64.

12 Were there other assignments that  
13 were made to you for the QSIP that are listed on  
14 this document?

15 A. I see four to my name and three  
16 in conjunction with another department.

17 Q. Okay. And are these accurate?

18 A. What do you understand by  
19 accurate?

20 Q. You don't understand the word  
21 "accurate"?

22 A. I understand the word  
23 "accurate."

24 MR. ANDERTON: Objection.

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1 this document?

2 A. In respect to 13.1?

3 Q. Yes. Was that part of the  
4 assessment?

5 A. Part of it would have been  
6 there.

7 Q. Yes. And if you look a couple  
8 spaces down is there another listing of an  
9 assessment and mod complaint system. Do  
10 you see that?

11 A. One second. Yes.

12 Q. Was that part of the report  
13 that you sent to the QSD?

14 MR. ANDERTON: Objection.

15 I'm going to instruct the witness  
16 not to answer.

17 MR. BLIZZARD: Okay.

18 BY MR. BLIZZARD:

19 Q. Look at the next or skip a  
20 line, another one down there is also  
21 assigned to you. It says assess and mod  
22 returned goods and recall system. Do you  
23 see that?

24 A. Yes.

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1 Q. Was that part of your  
2 assignment?

3 MR. ANDERTON: Objection.

4 I instruct the witness not to  
5 answer.

6 BY MR. BLIZZARD:

7 Q. Was it part of the deliverables  
8 that you were given under the QSIP?

9 A. Yes.

10 Q. When did you start working on  
11 that?

12 A. On which one of the?

13 Q. The one that says assess and  
14 mod returned goods and recall system.

15 A. I do not remember when I  
16 started working on that.

17 Q. Do you see a few lines down  
18 that you were also assigned assess and mod  
19 internal audit system? That was, you were  
20 assigned that along with Eng; correct?

21 A. Yes.

22 Q. What's Eng's first name?

23 A. Wanda.

24 Q. And when did you first start

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1 understand here is that a list needs to be  
2 provided biweekly for any CAPAs that are open.

3 MR. BLIZZARD: Okay.

4 BY MR. BLIZZARD:

5 Q. And it says CAPA database can  
6 be assessed now, accessed now to everyone;  
7 correct?

8 A. That's what the document reads.

9 Q. Okay. And who is everyone that  
10 can access the CAPA database?

11 A. I do not know.

12 Q. Okay. Do you know if any of  
13 this information was provided to FDA?

14 A. I do not know.

15 Q. Do you know if any of these  
16 assessments that you were working on were  
17 provided to Mylan?

18 MR. ANDERTON: Objection.

19 I'm going to -- let me think. You  
20 may answer the question but I instruct you not  
21 to reveal any of the contents of your report or  
22 the assessment that we've heard testimony about  
23 here today.

24 THE WITNESS: I do not know.

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1 about it?

2 A. Not specifically.

3 Q. Did you take any notes?

4 A. I do not remember taking notes.

5 Q. Did you try to commit to memory  
6 everything that he told you?

7 A. I cannot say that.

8 Q. What was the reason he told you  
9 about the contents of the warning letter?

10 MR. ANDERTON: Objection.

11 You may answer.

12 THE WITNESS: The reason is in the  
13 normal course of work.

14 MR. BLIZZARD: Okay.

15 BY MR. BLIZZARD:

16 Q. So, so that I'm understanding,  
17 you were not told about the contents of  
18 the warning letter as part of your  
19 assignment to assess and harmonize. You  
20 were instead told about this in the  
21 ordinary course of your work as an  
22 employee of Actavis Totowa.

23 MR. ANDERTON: Objection.

24 I instruct you to answer without

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1 revealing any of the contents of your  
2 assessment.

3 THE WITNESS: Yes.

4 MR. BLIZZARD: Okay. I'm not sure  
5 I have a clear answer.

6 BY MR. BLIZZARD:

7 Q. Yes, you were told this by  
8 Mr. Talbot after you started work in the  
9 regular course of your business for  
10 Actavis Totowa.

11 A. That is correct.

12 Q. Okay. So it wasn't part of the  
13 assessment process; correct?

14 A. No.

15 Q. Now we have a double negative.  
16 Was it a part of the assessment process?

17 A. No.

18 Q. Now, I'm going to show you what  
19 I'm going to mark as Exhibit 68 to your  
20 deposition?

21 (Exhibit [xx] was marked for  
22 identification.) 68.)

23 MR. ANDERTON: Has this been  
24 previously marked?